Amendments to the Claims

This listing of claims replaces all prior versions, and listings, of claims in the above-identified application:

1. (Original) An antiseptic composition comprising:

an antimicrobial agent selected from the group consisting of I_2, an iodophor, and a combination thereof, wherein the antimicrobial agent is present in an amount sufficient to provide an available iodine concentration of at least about 0.25 wt-%;

a hydroxycarboxylic acid buffer in an amount of at least about 5 wt-%;

water; and

a substantive film-forming polymer.

2. (Original) The antiseptic composition of claim 1 wherein a dry film of the composition is substantive.

3. (Original) The antiseptic composition of claim 1 wherein the antimicrobial agent is present in an amount sufficient to provide an available iodine concentration of no greater than about 1.0 wt-%.

4. (Original) The antiseptic composition of claim 1 wherein the hydroxycarboxylic acid buffer is present in an amount of no greater than about 15 wt-%.

5. (Original) The antiseptic composition of claim 1 wherein the composition has a Brookfield viscosity of no greater than about 1000 cps.

6. (Original) The antiseptic composition of claim 1 wherein the weight ratio of the film-

forming polymer to hydroxycarboxylic acid buffer is at least about 0.25:1.

7. (Original) The antiseptic composition of claim 1 wherein the composition reduces normal skin flora by at least about 1 log in 2 minutes on a dry human skin site using ASTM testing method E1173-93 and a 30-second scrub with gauze soaked in the composition using moderate pressure.

8. (Original) The antiseptic composition of claim 7 wherein the composition reduces normal skin flora by at least about 1.5 log in 2 minutes on a dry human skin site using ASTM testing method E1173-93 and a 30-second scrub with gauze soaked in the composition using moderate pressure.

9. (Original) The antiseptic composition of claim 1 wherein the composition reduces normal skin flora by at least about 0.5 log more than the same composition without the hydroxycarboxylic acid buffer present when tested on a dry human skin site using ASTM testing method E1173-93 measured 2 minutes after completion of a 30-second scrub with gauze soaked in the composition using moderate pressure.

10. (Original) The antiseptic composition of claim 1 wherein the antimicrobial agent is an iodophor comprising a carrier selected from the group consisting of a polyvinylpyrrolidone, a copolymer of N-vinyl lactam, a polyether glycol, a polyvinyl alcohol, a polycarboxylic acid, a polyacrylamide, a polysaccharide, and combinations thereof.

11. (Currently Amended) The antiseptic composition of claim ~~10~~ 63 wherein the iodophor is povidone-iodine.

12. (Original) The antiseptic composition of claim 11 wherein the iodophor is povidone-

iodine USP.

13. (Original) The antiseptic composition of claim 1 wherein the hydroxycarboxylic acid buffer comprises a compound represented by the formula:

$$R^1(CR^2OH)_n(CH_2)_mCOOH$$

wherein:

R^1 and R^2 are each independently H or a (C1-C8) saturated straight, branched, or cyclic alkyl group, a (C6-C12)aryl group, or a (C6-C12)aralkyl or alkaryl group wherein the alkyl groups are saturated straight, branched, or cyclic, whercin R^1 and R^2 may be optionally substituted with one or more carboxylic acid groups;

m = 0 or 1; and

n = 1-3.

14. (Original) The antiseptic composition of claim 13 wherein n = 1-2.

15. (Currently Amended) The antiseptic composition of claim ~~14~~ 1 wherein the hydroxycarboxylic acid buffer comprises lactic acid, malic acid, citric acid, 2-hydroxybutanoic acid, 3-hydroxybutanoic acid, mandelic acid, gluconic acid, tartaric acid, salicylic acid, lactones thereof, salts thereof, derivatives thereof, or combinations thereof.

16. (Original) The antiseptic composition of claim 15 wherein the hydroxycarboxylic acid buffer comprises lactic acid, malic acid, citric acid, or combinations thereof.

17. (Original) The antiseptic composition of claim 1 further comprising a (C1-C4)alcohol.

18. (Original) The antiseptic composition of claim 17 wherein the alcohol to water ratio is preferably at least about 60:40 by weight.

19. (Original) The antiseptic composition of claim 1 which is substantially free of volatile organic solvents.

20. (Original) The antiseptic composition of claim 1 wherein the composition has a closed-cup flash point of greater than about 60°C using ASTM testing method D3278-96.

21. (Original) The antiseptic composition of claim 1 wherein the film-forming polymer is prepared from at least about 50 wt-% of one or more hydrophobic monomers, based on the total weight of polymer.

22. (Withdrawn) The antiseptic composition of claim 1 wherein the film-forming polymer includes side-chain functional amine groups.

23. (Withdrawn) The antiseptic composition of claim 22 wherein the side-chain functional amine groups include protonated tertiary amines, quaternary amines, amine oxides, or combinations thereof.

24. (Withdrawn) The antiseptic composition of claim 23 wherein the film-forming polymer is prepared from at least about 15 wt-% of an amine group-containing monomer.

25. (Original) The antiseptic composition of claim 1 wherein the film-forming polymer is present in an amount of at least about 2 wt-%, based on the total weight of the antiseptic composition.

26. (Original) The antiseptic composition of claim 1 wherein a dry film of the composition is substantially nontacky.

27. (Original) The antiseptic composition of claim 1 wherein the ratio of hydroxycarboxylic acid buffer to antimicrobial agent is at least about 4.0 grams hydroxycarboxylic acid buffer per gram available iodine.

28. (Original) The antiseptic composition of claim 1 wherein the composition demonstrates a Draize score of zero in no greater than about 96 hours when tested according to the Rabbit Eye Irritation Test.

29. (Original) The antiseptic composition of claim 1 further comprising a surfactant.

30. (Original) The antiseptic composition of claim 29 wherein the surfactant is nonionic, anionic, or amphoteric.

31. (Withdrawn) The antiseptic composition of claim 30 wherein the surfactant is a nonionic surfactant with an HLB value of at least about 14.

32. (Withdrawn) The antiseptic composition of claim 31 wherein the surfactant is a nonionic surfactant with an HLB value of no greater than about 19.

33. (Original) The antiseptic composition of claim 32 further comprising an anionic or amphoteric surfactant.

34. (Original) The antiseptic composition of claim 35 wherein the anionic or amphoteric surfactant is selected from the group consisting of sulfonates, sulfates, phosphates, phosphonates,

and ammonium sulfonate amphoterics, and mixtures thereof.

35. (Withdrawn) The antiseptic composition of claim 34 wherein the anionic surfactant comprises a polyalkoxylate group.

36. (Withdrawn) The antiseptic composition of claim 30 wherein the surfactant is an amine oxide.

37. (Original) The antiseptic composition of claim 1 wherein a dry film of the composition adheres to a PSA-coated tape at a level of at least about 50% of the level of adhesion of the PSA-coated tape applied over dried BETADINE surgical scrub and paint solutions when measured using a 180 degree peel test after applying the PSA-coated tape to a dry film on dry human skin by rolling with a 2.1-kg, 5.1-cm wide roller, waiting at least 1 minute, and removing the PSA-coated tape at a peel angle of 180 degrees at a speed of 30.5 cm/minute.

38. (Original) The antiseptic composition of claim 1 wherein the composition is stable.

39. (Original) An antiseptic composition comprising:

an antimicrobial agent selected from the group consisting of I_2, an iodophor, and a combination thereof, wherein the antimicrobial agent is present in an amount sufficient to provide an available iodine concentration of at least about 0.25 wt-%;

a hydroxycarboxylic acid buffer in an amount of at least about 5 wt-%;

water; and

a film-forming polymer comprising hydrophilic and hydrophobic moieties.

40. (Withdrawn) An antiseptic composition comprising:

an iodophor in an amount of greater than 5 wt-%, wherein the iodophor comprises a

carrier selected from the group consisting of a polyvinylpyrrolidone, a copolymer of N-vinyl lactam, a polyether glycol, a polyvinyl alcohol, a polyacrylamide, a polysaccharide, and combinations thereof;

a hydroxycarboxylic acid buffer in an amount of at least about 5 wt-%; and

water.

41. (Original) An antiseptic composition comprising:

an antimicrobial agent selected from the group consisting of I_2, an iodophor, and a combination thereof, wherein the antimicrobial agent is present in an amount sufficient to provide an available iodine concentration of at least about 0.25 wt-%;

a hydroxycarboxylic acid buffer in an amount of at least about 5 wt-%;

water; and

a substantive film-forming polymer;

wherein a dry film of the composition is stable and substantive.

42. (Original) An antiseptic composition comprising:

an antimicrobial agent selected from the group consisting of I_2, an iodophor, and a combination thereof, wherein the antimicrobial agent is present in an amount sufficient to provide an available iodine concentration of at least about 0.25 wt-%;

a hydroxycarboxylic acid buffer in an amount of at least about 5 wt-%;

water; and

a substantive film-forming polymer;

wherein a dry film of the composition is stable and substantive and demonstrates one or more of the following characteristics:

reduces normal skin flora by at least about 1 log in 2 minutes on a dry human skin site using ASTM testing method E1173-93 and a 30-second scrub with gauze soaked in the composition using moderate pressure;

is substantially nontacky when in the form of a dry film;

demonstrates a Draize score of zero in no greater than about 96 hours according to the Rabbit Eye Irritation Test; or

adheres to a PSA-coated tape at a level of at least about 50% of the level of adhesion of the PSA-coated tape applied over dried BETADINE surgical scrub and paint solutions when measured using a 180 degree peel test after applying the PSA-coated tape to a dry film on dry human skin by rolling with a 2.1-kg, 5.1-cm wide roller, waiting at least 1 minute, and removing the PSA-coated tape at a peel angle of 180 degrees at a speed of 30.5 cm/minute.

43. (Original) An antiseptic composition comprising:

an antimicrobial agent selected from the group consisting of I_2, an iodophor, and a combination thereof, wherein the antimicrobial agent is present in an amount sufficient to provide an available iodine concentration of at least about 0.25 wt-% to about 1.0 wt-%;

a hydroxycarboxylic acid buffer in an amount of about 5 wt-% to about 15 wt-%;

water; and

a substantive film-forming polymer;

wherein the hydroxycarboxylic acid buffer comprises a compound represented by the formula:

$$R^1(CR^2OH)_n(CH_2)_mCOOH$$

wherein:

R^1 and R^2 are each independently H or a (C1-C8) saturated straight, branched, or cyclic alkyl group, a (C6-C12)aryl group, or a (C6-C12)aralkyl or alkaryl group wherein the alkyl groups are saturated straight, branched, or cyclic, wherein R^1 and R^2 may be optionally substituted with one or more carboxylic acid groups;

m = 0 or 1; and

n = 1-3.

44. – 53. (Cancelled)

54. (New) The antiseptic composition of claim 1 wherein the hydroxycarboxylic acid buffer is present in an amount in excess of 5 wt-%.

55. (New) The antiseptic composition of claim 54 wherein the hydroxycarboxylic acid buffer is present in an amount of at least about 6 wt-%.

56. (New) The antiseptic composition of claim 55 wherein the hydroxycarboxylic acid buffer is present in an amount of at least about 7 wt-%.

57. (New) The antiseptic composition of claim 1 wherein the hydroxycarboxylic acid buffer is present in a use concentration of an amount in excess of 5 wt-%.

58. (New) An antiseptic composition comprising:

an antimicrobial agent selected from the group consisting of I_2, an iodophor, and a combinations thereof, wherein the antimicrobial agent is present in an amount sufficient to provide an available iodine concentration of at least about 0.25 wt-%;

a hydroxycarboxylic acid buffer in an amount in excess of 5 wt-%;

water; and

a substantive film-forming polymer;

wherein a dry film of the composition is substantive.

59. (New) The antiseptic composition of claim 58 wherein the hydroxycarboxylic acid buffer

comprises a compound represented by the formula:

$$R^1(CR^2OH)_n(CH_2)_mCOOH$$

wherein:

R^1 and R^2 are each independently H or a (C1-C8) saturated straight, branched, or cyclic alkyl group, a (C6-C12)aryl group, or a (C6-C12)aralkyl or alkaryl group wherein the alkyl groups are saturated straight, branched, or cyclic, wherein R^1 and R^2 may be optionally substituted with one or more carboxylic acid groups;

m = 0 or 1; and

n = 1-3.

60. (New) The antiseptic composition of claim 58 wherein the hydroxycarboxylic acid buffer is present in an amount of at least about 6 wt-%.

61. (New) The antiseptic composition of claim 61 wherein the hydroxycarboxylic acid buffer is present in an amount of at least about 7 wt-%.

62. (New) The antiseptic composition of claim 58 wherein the hydroxycarboxylic acid buffer is present in a use concentration of an amount in excess of 5 wt-%.

63. (New) The antiseptic composition of claim 10 wherein the iodophore carrier is polyvinylpyrrolidone.